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EXAMINER	
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ART UNIT	PAPER NUMBER
3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/785,550	THURAU ET AL.	
	Examiner	Art Unit	
	HELEN NGUYEN	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-114* is/are pending in the application.

4a) Of the above claim(s) *8,9,17-19,44,45,51,60,61,67-81,89,90,97,98,101,106 and 108-112.* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,10-16,20-43,46-50,52-59,62-66,82-88,91-96,99-100,102-105,107, and 113-114* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

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DETAILED ACTION

1. This Office Action is responsive to the RCE filed 1/14/2008. Claims 1-114 are pending. Claims 1, 38, 58, 67, 82, 95, 103, 108, 113, and 114 are amended. Claims 8-9, 17-19, 44-45, 51, 60-61, 67-81, 89-90, 97-98, 101, 106, and 108-112 remain withdrawn. **Claims 1-7, 10-16, 20-43, 46-50, 52-59, 62-66, 82-88, 91-96, 99-100, 102-105, 107, and 113-114** remain under prosecution.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. **Claims 1-7, 10-16, 20-29, 34, 37, 39-40, 46, 48-50, 59, 82-88, 91-92, 95-96, 99-100, 103-105, and 113** are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon (US Pat No. 4673386) in view of Alden et al (US Pub No. 20050101979), further in view of Hagen et al (US Pat No. 6348043).

4. In regard to **Claims 1, 5-7, 11, 82, 86-88, 95-96, 103, and 113,** Gordon discloses a reservoir for use in a closed blood sampling system, the reservoir comprising:

a lower housing 13 having a rigid wall with an opening defining a variable volume chamber 14 due to movement of piston 15;

an open channel formed in a surface of the rigid wall having an inlet port and an exit port 17, 19 in fluid communication with the chamber and with the channel at separate locations thereof, the fluid communication between the exit port and chamber and channel being bidirectional, the channel in fluid communication with the chamber along at least a portion of the channel through an open top of the channel, best seen in Figure 1-2;

an upper housing coupled to the lower housing.

5. However, Gordon does not disclose a flexible membrane overlying at least part of the rigid wall to define the variable volume chamber. Alden et al disclose an analogous reservoir comprising:

a lower housing having a rigid wall including "first side" (308), best seen in Figure 3 bottom, with an opening opposite said wall;

a flexible membrane, referred to as "diaphragm" (310), overlying at least part of the rigid wall and sealingly secured thereto and secured to the lower housing closing off the opening off the open top of the channel to define a variable volume chamber (300) therebetween;

a channel formed in the rigid wall having an inlet port (302) and an exit port (316) and in fluid communication with the chamber;

an upper housing coupled to the lower housing, best seen in Figure 3 top on the side of "duct" (320);

the flexible membrane having a minimum volume position spaced closely adjacent the rigid wall to define a minimum volume at which fluid still flows between the inlet port and the exit port through the chamber, the flexible membrane being able to flex out of the minimum

volume position to an expanded volume position (¶0025) as an effective mechanism to control the flow of blood in and out of the reservoir.

6. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the piston in the reservoir of Gordon with a flexible membrane overlying at least part of the rigid wall to define the variable volume chamber above as taught by Alden et al as an equally as effective means to control the flow of blood into and out of the reservoir.

7. However, Gordon in combination with Alden et al do not disclose a drive surface adapted to engage against the flexible membrane to hold said membrane in the minimum volume position. Alden et al do disclose that mechanical means may be used to control movement of said flexible membrane (¶0025). Hagen et al disclose an analogous reservoir comprising a flexible membrane (70) coupled to a drive surface attached to a moveable plunger, referred to as "piston" (20), with a portion for manipulation by a user, wherein movement of the piston between two positions (Figure 18A and C) causes subsequent movement of the flexible membrane, best seen in Figures 18A-C (Col.10: 10-33).

8. Therefore, it would have been obvious to one of ordinary skill in the art to modify the reservoir of Gordon as modified by Alden et al to include a drive surface in the form of a moveable plunger having a first portion received through the upper housing with the drive surface coupled to the top of the flexible membrane and thus fluidly isolated from the chamber, said plunger having a second portion for manipulation by a user, as taught by Hagen et al, such that movement of the plunger in a first direction flexes the membrane toward the expanded volume position under fluid pressure of a patient's circulatory system to allow sampling and

movement in a second direction flexes the membrane toward the minimum volume position and holds the membrane in said position to discharge fluid from the reservoir, as an effective means to control the movement of the flexible membrane of Gordon and Alden et al.

9. In regard to **Claims 2, 59, 83,** Alden et al disclose the rigid wall including a stem adapted to cooperate with a mounting bracket for mounting to a support, best seen in Figure 2A and 2B.

10. In regard to **Claims 3, 39, 84**, Gordon and Alden et al disclose the rigid wall having a shape and the flexible membrane (310) generally conforming to the shape of the rigid wall.

11. In regard to **Claims 4, 40, 85**, Gordon in combination with Alden et al and Hagen et al disclose the rigid wall having a shape and the drive surface generally conforming to the shape of the rigid wall.

12. In regard to **Claims 10, 46, 91**, Gordon and Alden et al disclose the flexible membrane (310) having a lower surface, the rigid wall engaging against at least a portion of the lower surface in the minimum volume position.

13. In regard to **Claims 12, 48, 92**, Gordon in combination with Alden et al and Hagen et al disclose the flexible membrane 310 having an upper surface, the drive surface engaging against substantially the entire upper surface when in the minimum volume position.

14. In regard to **Claims 13-14, 49, 99, 104**, Gordon in combination with Alden et al and Hagen et al disclose the drive surface being positioned to move the membrane toward the rigid wall or channel so as to reduce the volume of the chamber in a first direction of movement of the drive surface causing a stepwise decrease in the volume of the chamber.

15. In regard to **Claims 15-16, 50, 100, 105**, Gordon in combination with Alden et al and Hagen et al disclose the flexible membrane being able to flex away from the rigid wall or channel to the expanded volume position in a second direction of movement of the drive surface causing a stepwise increase in the volume of the chamber.

16. In regard to **Claims 20-25, 27-29, 34, and 37**, Gordon in combination with Alden et al and Hagen et al disclose the invention above including a rigid wall with an upper edge, a flexible membrane with an upper edge, a housing with a lower edge, and a drive surface, all with a shape, but do not explicitly disclose a specific shape for said components. However, it would have been obvious to modify the rigid wall, flexible member, housing, and drive surface to have a shape such as bowl shaped, such that the rigid wall and flexible member are one of hemispherical, conical or oval bowl shape, the drive surface also bowl shaped, and the upper edge of the rigid wall and flexible member as well as the lower edge of the housing having a shape traversing at least one of a circular and elliptical path because it appears the invention of Gordon as modified by Alden et al and Hagen et al would perform equally well with those shapes and such a modification would have been considered a mere design choice which fails to patentably distinguish over Gordon, Alden et al, and Hagen et al.

17. In regards to **Claim 26**, Gordon discloses the inlet and exit ports 17, 19 being adjacent to the upper edge of the rigid wall.

18. **Claims 30-33, 35-36, 52-57, 93-94, 102, 107** are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon in view of Alden et al and Hagen et al, further in view of Bazell et al (US Pat No. 4370987).

19. In regard to **Claims 30, 52-53, 102, 107**, Gordon in combination with Alden et al and Hagen et al disclose the invention above but do not disclose the plunger having a knob for manipulation by a user. Bazell et al disclose a blood sampling device comprising an analogous plunger with a knob, referred to as "handle" (52), to allow easy access for manipulation by the user, best seen in Figure 5. Therefore, it would have been obvious to one of ordinary skill in the art to modify the plunger of Gordon as modified by Alden et al and Hagen et al to include a knob as taught by Bazell et al for ease of manipulation by the user during device use.

20. In regard to **Claims 31-33, 35-36, 54-57, 93-94**, Gordon in combination with Alden et al and Hagen et al disclose the invention above but do not disclose at least one of the housing and plunger adapted to fix the drive surface in certain positions. Bazell et al disclose a blood sampling device comprising a housing, referred to as "barrel" (20), and a plunger, referred to as "piston" (40) and “rod” (50), said housing including a detent or “locking member” (28) adapted to engage a recess on the plunger, or “projections” (54), best seen in Figure 1 and 4 (Col.3: 28-51), as an effective mechanism to hold an analogous drive surface in a number of positions.

Therefore, it would have been obvious to one of ordinary skill in the art to modify the invention of Gordon as modified by Alden and Hagen et al to such that the housing comprises a detent to engage a recess on the plunger, as taught by Bazell et al, to effectively secure the drive surface in a minimum or maximum volume position.

21. In regard to **Claims 38, 41-43, 47, 58, 62-66, 114,** Gordon in combination with Alden et al and Hagen et al disclose a closed blood sampling system comprising: tubing 40 adapted to be coupled between a fluid supply 41 and a circulatory system of a patient, best seen in Figure 2 of Gordon; a reservoir 11 disposed in the tubing, also seen in Figure 2 of Gordon, comprising a rigid wall, a flexible membrane, an inlet and exit port, and a drive surface, as fully elaborated in the combination of Gordon, Alden et al, and Hagen et al above; a sampling site through port 53 disposed in the tubing intermediate the patient and the reservoir to draw blood from the tubing, best seen in Figure 1 of Gordon (Col.3: 27-41); and a valve intermediate the fluid supply and the reservoir, wherein the valve is closed prior to flexing the membrane away from the minimum volume position to an expanded position in the manner above (Gordon Col.3: 15-26).

22. **Claims 1-7, 10-16, 20-29, 31, 34, 37, 82-88, 91-92, 95-96, 99-100, 103-105, and 113** are rejected under 35 U.S.C. 103(a) as being unpatentable over Alden et al (US Pub No. 20050101979) in view of Hagen et al (US Pat No. 6348043).

23. In regard to **Claims 1, 5-7, 11, 31, 82, 86-88, 95-96, 103, and 113,** Alden et al disclose a reservoir for use in a closed blood sampling system, the reservoir comprising:

a lower housing having a rigid wall including "first side" (308), best seen in Figure 3 bottom, with an opening opposite said wall;

a flexible membrane, referred to as "diaphragm" (310), overlying at least part of the rigid wall and sealingly secured thereto closing off the opening to define a variable volume chamber (300) therebetween;

a channel formed in the rigid wall having an inlet port (304) and an exit port (312) and in fluid communication with the chamber at separate locations thereof, the fluid communication between the exit port and chamber being bidirectional due to exit port 312 allowing both flow into the chamber as well as flow out of the chamber through exit channel 318 (¶0025 lines 15-18);

an upper housing coupled to the lower housing, best seen in Figure 3 top on the side of "duct" (320);

the flexible membrane having a minimum volume position spaced closely adjacent the rigid wall to define a minimum volume at which fluid still flows between the inlet port and exit port through the chamber, the flexible membrane being able to flex out of the minimum volume position to an expanded volume position (¶0025).

24. However, Alden et al do not disclose a drive surface adapted to engage against the flexible membrane to hold said membrane in the minimum volume position. Alden et al do disclose that mechanical means may be used to control movement of said flexible membrane (¶0025). Hagen et al disclose an analogous reservoir comprising a flexible membrane (70) coupled to a drive surface attached to a moveable plunger, referred to as "piston" (20), with a portion for manipulation by a user, wherein movement of the piston between two positions

(Figure 18A and C) causes subsequent movement of the flexible membrane, best seen in Figures 18A-C (Col.10: 10-33).

25. Therefore, it would have been obvious to one of ordinary skill in the art to modify the reservoir of Alden et al to include a drive surface in the form of a moveable plunger having a first portion received through the upper housing with the drive surface coupled to the top of the flexible membrane and thus fluidly isolated from the chamber, said plunger having a portion for manipulation by a user, as taught by Hagen et al, such that movement of the plunger in one direction flexes the membrane toward the expanded volume position to allow sampling and movement in a second direction flexes the membrane toward the minimum volume position and holds the membrane in said position to discharge fluid from the reservoir, as an effective means to control the movement of the flexible membrane of Alden et al.

26. In regard to **Claims 2, 83,** Alden et al disclose the rigid wall including a stem adapted to cooperate with a mounting bracket for mounting to a support, best seen in Figure 2A and 2B.

27. In regard to **Claims 3, 84**, Alden et al disclose the rigid wall having a shape and the flexible membrane (310) generally conforming to the shape of the rigid wall.

28. In regard to **Claims 4, 85**, Alden et al in combination with Hagen et al disclose the rigid wall having a shape and the drive surface generally conforming to the shape of the rigid wall.

29. In regard to **Claims 10, 91**, Alden et al disclose the flexible membrane (310) having a lower surface, the rigid wall engaging against at least a portion of the lower surface in the minimum volume position.

30. In regard to **Claims 12, 92**, Alden et al in combination with Hagen et al disclose the flexible membrane having an upper surface, the drive surface engaging against substantially the entire upper surface when in the minimum volume position.

31. In regard to **Claims 13-14, 99, 104**, Alden et al in combination with Hagen et al disclose the drive surface being positioned to move the membrane toward the rigid wall or channel so as to reduce the volume of the chamber stepwise in a first direction of movement of the drive surface.

32. In regard to **Claims 15-16, 100, 105**, Alden et al in combination with Hagen et al disclose the flexible membrane being able to flex away from the rigid wall or channel to the expanded volume position in a second direction of movement of the drive surface causing a stepwise increase in the volume of the chamber.

33. In regard to **Claims 20-29, 34, and 37**, Alden et al in combination with Hagen et al disclose the invention above including a rigid wall with an upper edge, a flexible membrane with an upper edge, a housing with a lower edge, and a drive surface, all with a shape, but do not explicitly disclose a specific shape for said components. However, it would have been obvious

to modify the rigid wall, flexible member, housing, and drive surface to have a shape such as bowl shaped, such that the rigid wall and flexible member are one of hemispherical, conical or oval bowl shape, the drive surface also bowl shaped, and the upper edge of the rigid wall and flexible member as well as the lower edge of the housing having a shape traversing at least one of a circular and elliptical path because it appears the invention of Alden et al as modified by Hagen et al would perform equally well with those shapes and such a modification would have been considered a mere design choice which fails to patentably distinguish over Alden et al in combination with Hagen et al.

34. Similarly, in regards to **Claim 26**, it would have been obvious to modify the position of the inlet and exit ports of Alden et al as modified by Hagen et al to be adjacent to the upper edge of the rigid wall for the same reasons.

35. **Claims 30, 32-33, 35-36, 93-94, 102, 107** are rejected under 35 U.S.C. 103(a) as being unpatentable over Alden et al in view of Hagen et al, further in view of Bazell et al (US Pat No. 4370987).

36. In regard to **Claims 30, 102, 107**, Alden et al in combination with Hagen et al disclose the invention above but do not disclose the plunger having a knob for manipulation by a user. Bazell et al disclose a blood sampling device comprising an analogous plunger with a knob, referred to as "handle" (52), to allow easy access for manipulation by the user, best seen in Figure 5. Therefore, it would have been obvious to one of ordinary skill in the art to modify the

plunger of Alden et al as modified by Hagen et al to include a knob as taught by Bazell et al for ease of manipulation by the user during device use.

37. In regard to **Claims 32-33, 35-36, 93-94**, Alden et al in combination with Hagen et al disclose the invention above but do not disclose at least one of the housing and plunger adapted to fix the drive surface in certain positions. Bazell et al disclose a blood sampling device comprising a housing, referred to as "barrel" (20), and a plunger, referred to as "piston" (40) and "rod" (50), said housing including a detent or "locking member" (28) adapted to engage a recess on the plunger, or "projections" (54), best seen in Figure 1 and 4 (Col.3: 28-51), as an effective mechanism to hold an analogous drive surface in a number of positions. Therefore, it would have been obvious to one of ordinary skill in the art to modify the invention of Alden as modified by Hagen et al to such that the housing comprises a detent to engage a recess on the plunger, as taught by Bazell et al, to effectively secure the drive surface in a minimum or maximum volume positions.

38. **Claims 38-43, 46-50, 58-59, 62-66, and 114** are rejected under 35 U.S.C. 103(a) as being unpatentable over Alden et al in view of Hagen et al, further in view of Simpson et al (US Pat No. 5002066).

39. In regard to **Claims 38, 58, 64, 114,** Alden et al in combination with Hagen et al disclose the blood sampling system comprising a reservoir above but do not disclose the system including tubing adapted to be coupled between a fluid supply and a circulatory system of a patient, nor a

valve. Simpson et al disclose a closed blood sampling apparatus comprising tubing adapted to be coupled between a fluid supply (16) and a circulatory system of a patient, a sampling site (29) disposed in the tubing intermediate the patient, and a valve, referred to as "stopcock" (11), which is closed prior to sampling blood, as well as a "T-connector" (27) used along with a "storage syringe" (35) assembly that functions analogously to said reservoir, best seen in Figure 1 (Col.3), as an effective method and system to sample blood.

40. Therefore, it would have been obvious to one of ordinary skill in the art to modify the invention of Alden et al as modified by Hagen et al to include tubing coupled between a fluid supply and a circulatory system of a patient so that a sampling site is disposed in the tubing intermediate the patient along with a valve that is closed prior to sampling blood, as taught by Simpson et al, and to sample the blood using the reservoir of Alden et al in combination with Hagen et al, as an effective method and apparatus to draw blood.

41. **Claims 52-57** are rejected under 35 U.S.C. 103(a) as being unpatentable over Alden et al in view of Hagen et al, further in view of Simpson et al, even further in view of Bazell et al.

42. Alden et al in combination with Hagen et al and Simpson et al disclose the invention above but do not disclose the plunger with a knob or a recess to fixedly secure the drive surface by engaging a detent in the housing. Bazell et al disclose a plunger with a knob and a recess and the housing with a detent, as further described above. Therefore, it would have been obvious to one of ordinary skill in the art to modify the invention of Alden et al as modified by Hagen et al and Simpson et al to include a knob and recess on the plunger and detent on the housing, as

taught by Bazell et al, to improve the sampling device for the reasons previously explained above.

Response to Arguments

43. Applicant's arguments with respect to Claims 1-7, 10-16, 20-43, 46-50, 52-59, 62-66, 82-88, 91-96, 99-100, 102-105, 107, and 113-114 have been fully considered but they are not persuasive.

44. While the Examiner does not necessarily agree with Applicant's arguments that Alden et al do not disclose fluid communication between the exit port and chamber being bidirectional due to the disclose of port 312 as a check valve, the Examiner has set forth new grounds of rejection above using at least Gordon in an effort to advance the prosecution of the instant application.

45. It is noted that while a common definition of check valve is one in which there is unidirectional flow, it must be noted that Alden et al still explicitly disclose that "a single check valve (at the location 312) may be present controlling both flow into the chamber 300 via the blood transport capillary channel 304 and flow out of the chamber 300 into an optional alternate exit channel 318" (¶0025 lines 15-18). Thus, regardless of the use of the term "check valve," Alden et al still disclose said valve used to control flow into and out of the chamber, i.e. bidirectional flow. Reliance upon an explicit disclosure in a reference is stronger than the supposedly known definition of one word in the same reference.

46. Also, it is also noted that Alden et al still disclose the inlet port 304 and the exit port 312 at separate locations thereof wherein at least one portion of both ports are located a location that

is not the location of the other, i.e. separate locations, wherein the term location is defined simply as "a point or extent in space" (www.dictionary.com). It is noted that while Applicant contends that the chamber would not form part of the pressure path in Alden et al (remarks p.30), such limitations are not presently claimed. Thus, it is maintained that Alden et al teach the invention as claimed and elaborated above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HELEN NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on Monday - Friday, 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. N./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736